EXHIBIT 6

TO DECLARATION OF DANIEL K. GREEN IN SUPPORT OF DEPOMED'S MOTIONS IN LIMINE

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF NEW JERSEY

DEPOMED, INC., Plaintiff, v. ACTAVIS ELIZABETH LLC, ACTAVIS, INC., INCEPTA PHARMACEUTICALS CO., LTD., and ABON PHARMACEUTICALS LLC, Defendants.	)	Civil Action No. 12-CV-01358 JAP (TJB)
DEPOMED, INC., Plaintiff, v. ZYDUS PHARMACEUTICALS (USA), INC., and CADILA HEALTHCARE LIMITED D/B/A ZYDUS CADILA, Defendants.	)	Civil Action No. 12-CV-02813 JAP (TJB)

VIDEOTAPED DEPOSITION OF DAVID R. FRIEND
New York, New York
Friday, March 28, 2014

Reported by:
Eileen Mulvenna, CSR/RMR/CRR
JOB No. 1834253
PAGES 1 - 193

March 28, 2014

8:31 a.m.

VIDEOTAPED DEPOSITION of DAVID R. FRIEND, taken by Plaintiffs, held at the offices of McDermott, Will & Emery, 340 Madison Avenue, New York, New York, before Eileen Mulvenna, CSR/RMR/CRR, Certified Shorthand Reporter, Registered Merit Reporter, Certified Realtime Reporter and Notary Public of the State of New York.

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STIPULATIONS

IT IS HEREBY STIPULATED AND AGREED, by and between the attorneys for the respective parties herein, that filing and sealing be and the same are hereby waived.

IT IS FURTHER STIPULATED AND AGREED that all objections, except as to the form of the question, shall be reserved to the time of the trial.

IT IS FURTHER STIPULATED AND AGREED that the within deposition may be signed and sworn to before any officer authorized to administer an oath, with the same force and effect as if signed and sworn to before the officer before whom the within deposition was taken.

there are insufficient data and other data that I cite in my report that indicate that it is unlikely the dosage forms are retained in the stomach to the extent that is set forth by the claims put forward by Depomed. 09:27:45 09:27:50 09:27:56 09:28:00 09:28:02

Q. You used the term "several hours." What quantity of time were you applying in making that assessment? 09:28:06 09:28:08 09:28:12

A. I would say that probably minimally four hours, up to eight or nine. 09:28:20 09:28:26

Q. Okay. Having looked at the data, is it your opinion as an expert that an Actavis ANDA product could not be retained for four hours if administered to a patient in a fed state? 09:28:46 09:28:58 09:29:04 09:29:08 09:29:12

A. Okay. You're asking is it possible that an Actavis product could be retained up to four hours? 09:29:20 09:29:22 09:29:27

Q. (Nods head in the affirmative.) 09:29:30

A. It's -- it's possible. 09:29:35

Q. Now, paragraph 16, you provide a second opinion that Actavis does not infringe the four asserted claims of the '280 patent, "because Depomed's experts failed to demonstrate that the Actavis ANDA products 09:30:03 09:30:08 09:30:11 09:30:14 09:30:17

remain substantially intact until substantially all of the gabapentin is released." 09:30:21 09:30:24 09:30:27

Do you see that? 09:30:28

A. Yes. 09:30:29

Q. And do you have an independent opinion on whether the Actavis ANDA products do or do not remain substantially intact until substantially all of the gabapentin is released? 09:30:29 09:30:33 09:30:37 09:30:41 09:30:43

A. Yes. 09:30:45

Q. What is it? 09:30:46

A. That there is measurable and, depending on time, considerable loss of polymer consistent with erosion of the matrix. 09:30:49 09:30:54 09:30:57

Q. And so it's your opinion -- in addition to, in your view, that Depomed's experts have not demonstrated it, it is your independent opinion that the dosage form does not remain substantially intact until substantially all the gabapentin is released? 09:31:06 09:31:09 09:31:13 09:31:16 09:31:18 09:31:20

A. Yes. 09:31:25

Q. Is there any reason why you didn't expressly state that opinion in paragraph 16? 09:31:30 09:31:31 09:31:34

accurate, yes. 11:25:40

Q. And any part of that you would 11:25:41

disagree with? 11:25:44

A. I would -- I don't disagree with 11:25:48

the statement, which I can barely see, 11:25:55

"proximal small bowel" because data support 11:25:58

uptake from the lower small bowel as well. 11:26:03

Q. And when you understand the term 11:26:09

"small bowel," what do you understand those 11:26:11

parts of the small intestine to encompass? 11:26:14

A. Essentially, from the -- just 11:26:18

past the pylorus to the ileocecal valve, the 11:26:23

entire small intestine. 11:26:28

Q. Now, Doctor, in your report, 11:27:22

we've talked about the -- for the background, 11:27:29

the scientific background, Section 7. And 11:27:32

then in Section 8, which we've discussed a 11:27:36

portion of, but we haven't discussed all of 11:27:38

it, you're discussing the asserted claims of 11:27:40

the '280 patent; correct? 11:27:44

A. Correct. 11:27:47

Q. Okay. Now, in Section A at 11:27:57

page 17, you write, in the first sentence, 11:28:03

"The court construed 'is of a size exceeding 11:28:11

the pyloric diameter in the fed mode to 11:28:16

promote retention in the stomach during said fed mode' of Claim 1 to mean 'such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours.'" 11:28:20 11:28:20 11:28:26 11:28:28 11:28:31

Is that accurate? 11:28:34

A. Yes. 11:28:38

Q. And what you're referring there to is a specific claim term in the '280 patent, Claim 1; correct? 11:28:39 11:28:42 11:28:45

A. Correct. 11:28:47

Q. And that claim term that the court was construing is "of a size exceeding the pyloric diameter in the fed mode to promote retention in the stomach during said fed mode"? 11:28:48 11:28:50 11:28:54 11:28:58 11:29:02

A. Yes. 11:29:05

Q. Now, you say -- you cite to "See paragraph 33 above." I'm pretty sure that's going to be your claim construction section. 11:29:10 11:29:13 11:29:18

A. Yes. 11:29:22

Q. And there on page 10, you have the same claim term language. Next to '280, the first quoted claim term language; correct? 11:29:23 11:29:25 11:29:33

A. Yes. 11:29:37

Q. And in the right-hand column, you put forth the court's construction. 11:29:38 11:29:40

A. Yes. 11:29:44

Q. And your understanding, as an expert, is that you are to apply that construction of the court to the evidence; correct? 11:29:45 11:29:47 11:29:49 11:29:52

A. Yes. 11:29:56

Q. And the court's construction is as set forth right there on page 10 in the right-hand column in the '280; correct? 11:30:01 11:30:04 11:30:06

A. Yes. 11:30:11

Q. And you, of course, read the court's Markman opinion; correct? 11:30:19 11:30:21

A. Yes. 11:30:25

MR. GAEDE: And let me mark as Exhibit 9 the court's Markman opinion. 11:30:31 11:30:34

THE REPORTER: I think it's 10. 11:30:41

MR. GAEDE: You're right. Thank you. 11:30:41 11:30:42

(Friend Exhibit 10, No Bates numbers, Markman Opinion, marked for identification.) 11:31:02 11:31:02 11:31:02

BY MR. GAEDE: 11:31:02

Q. Do you recognize Exhibit 10? 11:31:21

A. Yes. 11:31:23

Q. Could you turn your attention, please, to page 9 of the Markman order. 11:31:24 11:31:25

A. Okay. 11:31:34

Q. You see in the first paragraph there at the top of the page, in the middle of it, it makes reference to "Defendants, on the other hand, seek the following construction: 'Is of a size exceeding the pyloric diameter in the fed mode such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for the duration of drug delivery.'" 11:31:35 11:31:37 11:31:39 11:31:45 11:31:47 11:31:54 11:31:56 11:31:58 11:32:01

Do you see that? 11:32:06

A. Yes. 11:32:08

Q. And the "defendants" -- by that you understand is Actavis in part; correct? 11:32:09 11:32:11

A. Yes. 11:32:16

Q. And so you understood that the defendants were proposing to the court that it construe this limitation to include an element of "a size exceeding the pyloric diameter in the fed mode," didn't you? 11:32:16 11:32:18 11:32:21 11:32:24 11:32:27

A. That would be my understanding, yes. 11:32:30 11:32:31

Q. And the court then, after that, said, "For the reasons discussed above, the court finds no reason to depart from its earlier construction and adopts its construction from the Sun Pharma case, supra." 11:32:33 11:32:35 11:32:37 11:32:40 11:32:43

Do you see that? 11:32:49

A. Yes. 11:32:49

Q. And what they adopted was -- is the construction that is set forth in your expert report at page 10, "such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours." 11:32:50 11:32:51 11:32:57 11:33:05 11:33:06 11:33:09

Correct? 11:33:13

A. Correct. 11:33:14

Q. Now, in your paragraph 42 of your expert report, you write, "As the claim language makes clear, however, this" -- 11:33:16 11:33:26 11:33:38

A. Excuse me. Where are you reading? 11:33:41 11:33:43

Q. I'm sorry, paragraph 42. 11:33:43

A. Oh, paragraph 42. I'm sorry. I thought you meant page 42. I'm sorry. My fault. 11:33:45 11:33:47 11:33:50

Q. No problem. 11:33:51

A. Okay. 11:33:54

Q. Okay. Now, in paragraph 42 after you quote the court's construction -- 11:33:55 11:34:01

Are you there? 11:34:06

A. Almost. 11:34:06

Q. Sorry. Page 17. I should give you the page reference. 11:34:07 11:34:10

A. That would be easier. Okay. 11:34:11

Q. Let's start over. 11:34:14

Paragraph 42 of your expert report, second sentence, you write, "As the claim language makes clear, however, this must be due to the dosage form being of a size that is larger than the pyloric diameter in the fed mode." 11:34:16 11:34:18 11:34:22 11:34:26 11:34:28 11:34:31

Do you see that? 11:34:32

A. Yes. 11:34:33

Q. That's not in the court's construction, is it? 11:34:34 11:34:43

A. Not word-for-word, no. 11:34:45

Q. And, in fact, the defendants provided that specific element of the dosage form being of a size that is larger than the pyloric diameter, and you noted that the court did not accept that in the construction of 11:34:46 11:34:49 11:34:53 11:34:56 11:34:59

this element; correct? 11:35:01

A. Yes. 11:35:06

Q. Nonetheless, you applied in your analysis a requirement that the dosage form be of a size that is larger than the pyloric diameter in the fed mode; correct? 11:35:09 11:35:13 11:35:20 11:35:23

A. Correct. 11:35:26

Q. Doctor, when the stomach -- the peristaltic wave moves through the stomach and there's food in the stomach and the pylorus clenches, what's the diameter of it? 11:35:31 11:35:36 11:35:39 11:35:45

A. It can be variable. 11:35:48

Q. What is it? 11:35:49

A. I took that size to be about 12 or 13 millimeters in diameter on average. 11:35:52 11:36:04

Q. That's when the pylorus is clenched? 11:36:07 11:36:09

A. No, I didn't consider clenching versus unclenching. 11:36:15 11:36:19

Q. And you're aware, though, that in the digestive process of the stomach, as food is pushed by the peristaltic waves against the pylorus, it is clenched? 11:36:21 11:36:22 11:36:25 11:36:29

A. For a short period of time possibly, yes. 11:36:36 11:36:38

Q. We looked at articles that say that; right, Doctor? 11:36:39 11:36:41

A. Yes. 11:36:42

Q. And you didn't consider what the diameter was of the pylorus in the fed state when it is clenched; correct? 11:36:43 11:36:45 11:36:50

A. No. 11:36:55

Q. And nothing in the court's construction says that it is the diameter of the pylorus in a resting state, is it? 11:37:02 11:37:04 11:37:07

A. It doesn't say so specifically, no. 11:37:17 11:37:19

Q. Okay. Now, you've adopted a general notion reflected in Dr. Annunziata's report that the size of a fully relaxed pylorus is 12.8 millimeters plus or minus 7 millimeters depending upon the individual; correct? 11:37:22 11:37:29 11:37:33 11:37:40 11:37:43 11:37:49

A. In the fed state, yes. 11:37:50

Q. And you write in your report, at paragraph 45, "Depomed's experts state that the size of the pylorus during the fed mode is 12.8 millimeters plus or minus 7 millimeters." 11:38:02 11:38:04 11:38:08 11:38:11

And you cite Dr. Annunziata's report at paragraph 45. 11:38:18 11:38:20

A. Probably not as well as you could. 12:04:38 12:04:42

Q. Is it fair to say you relied upon the lawyers for this description in paragraph 59? 12:04:44 12:04:45 12:04:47

A. In this particular case, yes. 12:04:51

Q. Okay. This is really a legal argument, isn't it, sir, as you read it? 12:04:54 12:05:01

MR. LANDMON: Objection; vague and ambiguous. 12:05:05 12:05:06

THE WITNESS: I'm not a lawyer so I can't give you an opinion about its being a legal argument. 12:05:07 12:05:08 12:05:12

BY MR. GAEDE: 12:05:16

Q. Can you point to me the scientific opinion in paragraph 59? 12:05:16 12:05:17

(Witness peruses the exhibit.) 12:05:35

A. I don't see a scientific opinion, no. 12:05:39 12:05:41

Q. Now, if we could turn your attention to page 27 and 28 of your expert report. 12:05:49 12:05:51 12:05:58

A. Okay. 12:06:03

Q. Now, here in paragraph 60 of your report, you applied the construction to 12:06:07 12:06:13

"release of substantially all of said drug after such immersion" to mean "at least 80 percent of the drug has been released after eight hours of immersion in gastric fluid." 12:06:17 12:06:21 12:06:24 12:06:26

Do you see that? 12:06:30

A. Yes. 12:06:31

Q. And that's the test that you apply in assessing whether the Actavis 600 milligram product releases substantially all of the gabapentin from the dosage form at eight or ten hours; correct? 12:06:32 12:06:34 12:06:38 12:06:42 12:06:45

A. Correct. 12:06:50

Q. And when you applied eight hours for Claim 1, do you see that limitation in Claim 1? 12:06:54 12:06:58 12:07:00

(Witness peruses the exhibit.) 12:07:17

A. No. 12:07:25

Q. And you have some patents, don't you, sir? 12:07:27 12:07:30

A. Yes. 12:07:31

Q. So you've read patents before? 12:07:31

A. Yes. 12:07:34

Q. And you understand that we're looking at claims; right? 12:07:34 12:07:35

A. Yes. 12:07:38

Q. And you understand the concept of an independent or dependent claim? 12:07:39 12:07:40

A. I do. 12:07:43

Q. Could you turn your attention to Claim 46 of the '280 patent. 12:07:44 12:07:47

A. Okay. 12:07:59

Q. And would you read Claim 46 into the record, please. 12:08:02 12:08:05

A. "A dosage form in accordance with Claim 1 in which said dosage form releases substantially all of said drug within about eight hours after immersion in gastric fluid." 12:08:06 12:08:09 12:08:12 12:08:14

Q. There we have an eight-hour limitation in Claim 46, don't we? 12:08:18 12:08:20

A. Correct. 12:08:23

Q. But we don't in Claim 1, do we? 12:08:24

A. Not explicitly, no. 12:08:29

Q. And in the middle of paragraph 60 of your expert report, you make reference to "Notably in that case, the court construed a very similar claim term in the '280 patent, 'while releasing substantially all of said drug within said stomach where said drug is maintained in an acidic environment' to mean 'at least 80 percent of the drug has been 12:08:38 12:08:40 12:08:46 12:08:51 12:08:53 12:08:58 12:09:00 12:09:04

released after eight hours of immersion in gastric fluid.'" 12:09:08 12:09:11

A. Yes. 12:09:15

Q. It's not the same claim as Claim 1, is it? 12:09:16 12:09:17

A. I believe in this particular case, I was relying on the agreed-upon definition of -- or interpretation of that element. 12:09:23 12:09:24 12:09:27 12:09:30

MR. GAEDE: Why don't we go off the record for a second. 12:09:51 12:09:52

THE VIDEOGRAPHER: The time on the video monitor is 12:10 p.m. We're off the record. 12:09:55 12:09:56 12:09:58

(Luncheon recess from the record.) 12:10:08 12:10:08

A F T E R N O O N S E S S I O N 12:52:11

THE VIDEOGRAPHER: We are back on the record. The time on the video monitor is 12:54 p.m. 12:54:34 12:54:34 12:54:36

DAVID FRIEND, 12:54:37

having been previously sworn, resumed the stand and testified further as follows: 12:54:37 12:54:37

EXAMINATION (Cont'd.) 12:54:37

BY MR. GAEDE: 12:52:11

Q. Doctor, having had a chance to think about any of your answers from this morning, do you wish to change any of them? 12:54:40 12:54:41 12:54:43

A. Not at this point. 12:54:46

Q. Doctor, we were talking about the dissolution -- 12:54:56 12:55:00

A. Right. 12:55:01

Q. -- criteria with respect to the '280 patent that is discussed at pages 27 and 28 of your expert report. 12:55:01 12:55:05 12:55:08

A. Okay. 12:55:15

Q. In paragraph 60, where you have the requirement of the eight hours of immersion in gastric fluid . . . 12:55:15 12:55:19 12:55:22

A. The statement? 12:55:29

Q. Yes. The first sentence. 12:55:31

A. First sentence, yes. 12:55:33

Q. And you reference paragraph 32 above. So if we go to paragraph 32 above in your expert report, which is Exhibit 1 to your deposition, there in paragraph 32 at page 8 -- 12:55:34 12:55:36 12:55:42 12:55:44

A. Yes. 12:55:59

Q. -- there is claim term language. It says, "Releases substantially all of said drug after such immersion." 12:55:59 12:56:01 12:56:06

A. Yes. 12:56:08

Q. And it refers to 61, correct, term number? 12:56:08 12:56:13

A. Yes. 12:56:13

Q. And you and I both agree that in Claim 1 of the '280 patent, there's no express claim language that says at about -- about or within eight hours; correct? 12:56:14 12:56:18 12:56:21 12:56:24

A. Not in Claim 1. 12:56:27

Q. And in 61 here and the document you cite, which is Exhibit 11 to your expert report -- if you need to confirm yourself on that, that's at page 10. It follows your chart. 12:56:31 12:56:37 12:56:42 12:56:44 12:56:47

A. Yes. 12:56:51

Q. So let me mark as Exhibit 12 12:56:52

Exhibit 11 to your expert report, which is the revised joint claim construction and prehearing statement, which is referenced and attached to your expert report. 12:56:53 12:56:58 12:57:00 12:57:05

(Friend Exhibit 12, No Bates numbers, Exhibit 11 to expert report of David R. Friend, Ph.D., marked for identification.)

(Witness peruses the exhibit.) 12:57:21

BY MR. GAEDE: 12:57:21

Q. If you look there at Claim -- at Item 61, the last page of Exhibit 12 to your deposition. 12:57:34 12:57:35 12:57:40

A. Okay. 12:57:53

Q. You'll see Item 61? 12:57:54

A. Yes. 12:57:56

Q. And "Claim Term" underneath -- above that? 12:57:56 12:57:59

MR. LANDMON: Above it. 12:58:00

THE WITNESS: Above it, yes. 12:58:01

Q. And the claim term that appears there in 61 says, "Releases substantially all of said drug without [sic] about eight hours of such immersion." 12:58:01 12:58:03 12:58:06 12:58:09

I think that should be "within." 12:58:10

A. Yes, yes. 12:58:11

Q. And in your expert report where it has the claim term next to 61, "Releases substantially all of said drug after such immersion," that's not the same claim term, is it? 12:58:14 12:58:18 12:58:23 12:58:25 12:58:29

A. I chose to use the agreed claim construction. 12:58:31 12:58:35

Q. For the claim term "Releases substantially all of said drug within about eight hours after such immersion"; correct? 12:58:37 12:58:39 12:58:42

A. Yes. 12:58:45

Q. That came from a different patent, didn't it? 12:58:45 12:58:47

A. Excuse me? 12:58:50

Q. That claim term comes from a different patent, doesn't it? 12:58:52 12:58:54

A. I can't say that it does or doesn't without further review. 12:58:56 12:58:58

Q. So, clearly, if the eight-hour requirement is not in Claim 1 of the '280 patent, your opinions on that claim with respect to the dissolution element would change; correct? 12:59:02 12:59:05 12:59:08 12:59:12 12:59:15

A. Possibly. 12:59:18

Q. You do agree that at least 80 percent of the drug is shown to be released from the dosage forms in the in vitro studies; correct? 12:59:28 12:59:30 12:59:35 12:59:38

A. You're saying that the in vitro dissolution studies are carried out to at least 80 percent of drug release? 12:59:41 12:59:43 12:59:46

Q. Yes. 12:59:48

A. Yes, I believe most of those studies are. 12:59:50 12:59:52

MR. GAEDE: Why don't we mark as Exhibit 13 a document entitled, "Quantitative Tablet Swelling Study In Vitro Dissolution and Qualitative Tablet Imaging Study of Gabapentin Tablets." It's at DEPOACT0114326.1 through DEPOACT0114350.1. 13:00:22 13:00:23 13:00:29 13:00:32 13:00:36 13:00:38 13:00:46

(Friend Exhibit 13, Bates Nos. DEPOACT0114326.1 through DEPOACT0114350.1., Quantitative Tablet Swelling Study, marked for identification.) 13:00:53 13:00:53 13:00:53 13:00:53 13:00:53

Q. You've reviewed Exhibit 13 before, sir? 13:01:13 13:01:15

A. Yes. 13:01:19

Q. And as reflected in page 9 and page 11 of the report, the Actavis 300 milligram and 600 milligram tablets that are the subject of this litigation certainly release more than 80 percent of the gabapentin that's contained in the dosage forms; correct? 13:01:28 13:01:33 13:01:38 13:01:41 13:01:44 13:01:48

A. Yes. In this particular experiment, yes. 13:01:56 13:01:58

Q. And Actavis' own dissolution data that is submitted to the FDA also shows that both dosage forms release more than 80 percent; correct? 13:02:00 13:02:03 13:02:06 13:02:08

A. I believe so. 13:02:13

Q. Now, since we're on dissolution studies, you also have an opinion here on Claim 45 of the '280 patent and Claim 26 of the '927 patent. If you need to see that, sir, it's at page 40 of your expert report. 13:02:15 13:02:17 13:02:22 13:02:37 13:02:40

A. Page 40? 13:02:43

Q. Yes. 13:02:44

(Witness peruses the exhibit.) 13:02:45

A. Okay. 13:02:49

Q. Now, before we go any further, do you have the '280 patent in front of you, sir? 13:02:51 13:02:59

A. Yes. 13:03:12

Q. If you could turn to Claim 45, please. 13:03:13 13:03:15

A. Okay. 13:03:20

Q. And that claim says, "A dosage form in accordance with Claim 1 in which said dosage form releases substantially all of said drug within about ten hours after immersion in gastric fluid." 13:03:22 13:03:25 13:03:28 13:03:31 13:03:36

Do you see that? 13:03:37

A. Yes. 13:03:38

Q. So it has the requirement of within about ten hours; correct? 13:03:40 13:03:42

A. Correct. 13:03:46

Q. And that doesn't mean exactly ten hours; correct? 13:03:46 13:03:48

A. That would be my understanding. 13:03:50

Q. Likewise, for Claim 26 in the '927 patent, where, as reflected on page 40 of your expert report, you quote it? 13:03:54 13:03:58 13:04:05

A. Yes. 13:04:09

Q. Claim 26 of the '92 [sic] patent states, "The method of Claim 17 wherein the dosage form provides administration of at least 85 percent weight of the gabapentin to be delivered over a period of about five to 12 13:04:10 13:04:13 13:04:15 13:04:18 13:04:20

hours"; correct? 13:04:23

A. Correct. 13:04:25

Q. That doesn't require exactly at 13:04:27

12 hours; correct? Or within -- 13:04:29

A. Within 12 hours. 13:04:39

Q. -- 12 hours. 13:04:40

A. Yes. 13:04:41

Q. Could be a little bit more; 13:04:41

right? 13:04:42

A. Very little more. 13:04:44

Q. But it's not 12 hours or less; 13:04:46

correct? 13:04:48

A. That would be one interpretation. 13:04:51

Q. Is that how you read the term "of 13:04:54

about"? 13:04:55

(Witness peruses the exhibit.) 13:05:04

A. Okay. So where does it say "of 13:05:11

about"? 13:05:13

Q. In Claim 26 of the '927 patent, 13:05:14

page 40, where you quote it. 13:05:19

(Witness peruses the exhibit.) 13:05:29

A. I don't see an "of about." 13:05:35

Q. Could I see your report. 13:05:41

A. (Handing.) 13:05:43

Q. It's in the quote -- 13:05:49

A. Oh, the quote. 13:05:51

Q. Paragraph 98, "period of about" (indicating). 13:05:52 13:05:58

A. Okay. 13:05:59

(Witness peruses the exhibit.) 13:06:00

A. "Of about," yes. 13:06:01

Q. And, again, that doesn't mean exactly at 12 or less, correct, by your understanding? 13:06:05 13:06:06 13:06:09

A. That could exceed somewhat or slightly beyond 12 hours, I agree. 13:06:11 13:06:14

Q. Okay. So let's take a look -- since we have the ten-hour data and the 12-hour data, we can do both at the same time if you're okay with that. 13:06:19 13:06:21 13:06:24 13:06:27

A. Okay. Yes. 13:06:29

Q. So first of all, in Exhibit 13, with respect to the ten-hour limitation in the '280 patent claim 45, we see clearly at page 9 for the 300 milligram Actavis tablet 80 percent is exceeded at ten hours; correct? 13:06:42 13:06:48 13:06:53 13:07:03 13:07:08

A. In this table, yes. 13:07:19

Q. And also in the data that is for the 600 milligram Actavis tablet on page 11 of Exhibit 13, at the ten-hour, it has the 13:07:21 13:07:22 13:07:30

Q. And there, in .1 HCl, we have one, two, three, four, five, six, seven, eight, nine, ten, 11, 12 -- hold on. Let me start over. I think I got that wrong. My eyesight's fading. Let me start over. 13:15:34 13:15:39 13:15:42 13:15:59 13:16:01

There at the 12-hour mark, we have one, two, three, four, five, six, seven, eight, nine, ten, 11 tablets are at 85 or above; correct? 13:16:04 13:16:06 13:16:08 13:16:17

A. Correct. 13:16:19

Q. And as reflected there, in .1 HCl, the average is 86 percent; correct? 13:16:23 13:16:26

A. Yes. 13:16:30

Q. And that exceeds the requirement, even by your interpretation of Claim 26 of the '927 patent, as having 85 percent or more release at 12 hours; correct? 13:16:31 13:16:33 13:16:37 13:16:40

A. Correct. 13:16:44

Q. And, of course, as we discussed with respect to the ten-hour, the 12-hour and even the 14-hour data, at each time point, you would expect there to be continued release of the drug from the dosage form beyond that point in time; correct? 13:16:59 13:17:01 13:17:03 13:17:06 13:17:09 13:17:12

A. That would be my conclusion, yes. 13:17:16

Q. Now, let's turn your attention to your opinion on "substantially intact" with respect to Claim 1 of the '280 patent reflected at pages 29 and 30 of your expert report. 13:18:54 13:18:56 13:19:00 13:19:03 13:19:05

A. Okay. 13:19:13

Q. Now, in paragraph 67, you write, "The court construed 'remains substantially intact' of Claim 1 to mean 'a polymeric matrix in which the polymer portion substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles.'" 13:19:20 13:19:26 13:19:31 13:19:38 13:19:39 13:19:42 13:19:45 13:19:49

Correct? 13:19:54

A. Correct. 13:19:54

Q. Now, do you read that construction as preventing any erosion of any of the polymers in the matrix? 13:19:55 13:19:58 13:20:04

A. Any of the polymers? 13:20:09

Q. Yes. 13:20:11

A. I would read it as substantially all of the polymers remain such that the dosage form maintains its shape and size. 13:20:14 13:20:17 13:20:22

Q. Until at least 80 percent of the 13:20:27

drug has been released? 13:20:29

A. Correct. 13:20:30

Q. And you would agree that there is contemplation that ultimately there will be dissolution of the polymers of the matrix -- of the polymeric matrix in the '280 patent; correct? 13:20:37 13:20:40 13:20:43 13:20:44 13:20:48

A. I would have to review the '280 patent to confirm that. 13:20:51 13:20:53

Q. You don't recall that? 13:20:55

A. Not offhand, no. 13:20:58

Q. Do you have the '280 patent there? It's Exhibit 11 to your deposition, if that helps on the exhibit number. 13:21:09 13:21:10 13:21:15

A. Here it is, yes. 13:21:17

Q. Great. 13:21:20

(Witness peruses the exhibit.) 13:21:21

Q. Now, could you turn your attention to Column 6 of the '280 patent. 13:21:40 13:22:00

A. Yes. 13:22:06

Q. There at Column 6, line 10 -- Are you there? 13:22:08 13:22:14

A. Yes. 13:22:14

Q. -- it says, "The matrix itself is solid prior to administration and, once 13:22:14 13:22:17

administered, remains undissolved in (i.e. is not eroded by) the gastric fluid for a period of time sufficient to permit a majority of the drug to be released by the solution diffusion process during the fed mode. The rate-limiting factor in the release of the drug is, therefore, controlled diffusion of the drug from the matrix rather than erosion, dissolving or chemical decomposition of the matrix." 13:22:19 13:22:24 13:22:27 13:22:29 13:22:32 13:22:35 13:22:37 13:22:39 13:22:42 13:22:45

A. Yes. 13:22:49

Q. The rate-controlling mechanism of release here in the Actavis tablets, what is it? 13:22:53 13:22:58 13:23:01

MR. LANDMON: Objection; beyond the scope of his expert report. 13:23:05 13:23:06

THE WITNESS: I don't have an opinion per se. 13:23:08 13:23:09

BY MR. GAEDE: 13:23:11

Q. Okay. Would you turn your attention, please, to Column 9 of the '280 patent. 13:23:11 13:23:28 13:23:31

A. Okay. 13:23:36

Q. There it -- it states, Column 9, line 15, "The particle will then dissolve" -- 13:23:36 13:23:40

withdraw that. Start over. 13:23:47

Column 9, line 15, it says, "The 13:23:49
particles will then slowly dissolve or 13:23:52
decompose. Complete dissolution or 13:23:53
decomposition may not occur until 24 hours or 13:23:55
more after the intended dosing period ceases, 13:23:59
although in most cases, complete dissolution 13:24:04
or decomposition will occur within ten to 24 13:24:07
hours after the dosing period." 13:24:10

Correct? 13:24:13

A. Correct. 13:24:15

Q. So as an expert, doesn't this 13:24:15
patent contemplate that there will be some 13:24:18
dissolution of the matrix -- of the matrix 13:24:21
polymers into the dissolution media while a 13:24:21
drug is being released? 13:24:25

A. I can't say what it would mean in 13:24:31
terms of what would happen under in vitro 13:24:36
dissolution test conditions. 13:24:40

Q. What do you mean you can't say 13:24:49
what it would mean in terms of what would 13:24:50
happen under in vitro dissolution test 13:24:52
conditions? 13:24:55

A. I would mean that it's -- okay. 13:25:14
I -- can you ask the question prior to that 13:25:37

one again, please. 13:25:39

Q. Sure. 13:25:43

As an expert, doesn't this patent 13:25:47
contemplate that there will be some 13:25:50
dissolution of the matrix polymers into the 13:25:51
dissolution media while a drug is being 13:25:54
released? 13:26:02

A. It's a possible interpretation -- 13:26:02
or anticipation. 13:26:03

Q. And one of ordinary skill in the 13:26:12
art using -- someone like yourself using HPMC 13:26:14
and POLYOX would understand, at the initial 13:26:19
hydration, there would be some dissolution of 13:26:25
some of the polymers off the surface of the 13:26:28
polymeric matrix; correct? 13:26:31

A. Yes, but not an amount that could 13:26:32
be easily determined in a short period of 13:26:34
time. 13:26:36

Q. And that's because, at that 13:26:37
initial hydration, then subsequent to that, a 13:26:41
gel will form; correct? 13:26:44

A. Yes. 13:26:47

Q. And then you would expect the 13:26:48
rate of dissolution of polymers off that gel 13:26:49
to slow over that initial rate of polymers 13:26:52

dissolving off the initially hydrated dry tablet; correct? 13:26:56 13:26:59

A. It's possible. 13:27:02

Q. And you have made no determination whether the erosion that you identify based on Dr. Park's report, i.e., dissolution of certain polymers into the media, affects the rate-controlling release mechanism of the dosage form; correct? 13:27:13 13:27:15 13:27:21 13:27:25 13:27:28 13:27:32

A. Can you restate that again. Thank you. 13:27:38 13:27:40

Q. You have made no determination whether the erosion that you identify based on Dr. Park's report, i.e., dissolution of certain polymers into the media, affects the rate-controlling release mechanism of the dosage form; correct? 13:27:40 13:27:42 13:27:47 13:27:50 13:27:53 13:27:56

A. I don't recall exactly, but I believe that Dr. Park did not look at dissolution of drug in those experiments. So I did not. 13:28:00 13:28:03 13:28:06 13:28:11

Q. And you did not ask Dr. Park to do so -- those experiments prior to rendering your opinions; correct? 13:28:42 13:28:44 13:28:47

A. Correct. 13:28:49

Q. And you have not performed that analysis; correct? 13:28:50 13:28:52

A. No. 13:28:53

Q. And you certainly had an opportunity to do so prior to submitting your expert report; correct? 13:28:56 13:28:57 13:29:00

A. That would be what, correlating dissolution of drug with erosion, running the Park experiment? 13:29:06 13:29:08 13:29:11

Q. You rely on some investigational data generated by Dr. Park. There's nothing that prevented you from doing investigation, either on your own or in connection with Dr. Park, to assess whether the rate-controlling release mechanism of the dosage form was affected by this polymer that you noted has been dissolved into the media? 13:29:15 13:29:18 13:29:20 13:29:23 13:29:25 13:29:27 13:29:30 13:29:33

A. I guess I would say there was nothing to promote me to want to do that. 13:29:39 13:29:40

Q. The good news, Doctor, I actually cut down the amount of documents that people want me to ask you questions about. 13:30:32 13:30:33 13:30:36

A. Much appreciated. Much appreciated. 13:30:38 13:30:40

Q. I'm actually trying on your 13:30:44

behalf. 13:30:46

(Pause from the record.) 13:30:46

Q. Okay. Now, we agree, with 13:31:11

respect to substantially intact, that that's 13:31:14

measured at 80 percent release of the drug; 13:31:16

correct? 13:31:18

A. Can you point out where that -- 13:31:21

Q. Page 29, 30 of your expert 13:31:23

report. 13:31:25

(Witness peruses the exhibit.) 13:31:30

A. Can you repeat the question. 13:31:35

Q. We agree that we look at the 13:31:36

requirement of substantially intact when 13:31:39

80 percent of the drug is released; correct? 13:31:42

A. Yes. 13:31:46

Q. Okay. 13:31:46

MR. GAEDE: Let me mark as 13:31:56

Exhibit 15 the expert report of Aeri 13:32:00

Park dated March 19, 2014. 13:32:03

(Friend Exhibit 15, No Bates 13:32:25

numbers, Expert report of Aeri Park, 13:32:25

Ph.D., marked for identification.) 13:32:25

BY MR. GAEDE: 13:32:25

Q. Doctor, you recognize Exhibit 15; 13:32:31

correct? 13:32:33

Q. Now, you looked at Dr. Tesfu's methods in her report; correct? 13:48:49 13:48:53

A. Yes. 13:48:57

Q. And what she has -- a process that she used and which -- she then took photographers of the dosage forms at various time points; correct? 13:48:58 13:49:00 13:49:03 13:49:05

A. Correct. 13:49:07

Q. And you don't provide any criticism of those methods that she used to gather that data, did you? 13:49:08 13:49:11 13:49:15

A. Specifically the pictures? 13:49:18

Q. Yes. 13:49:20

A. Ask that question one more time. Thank you. 13:49:23 13:49:25

Q. You don't provide any criticism of those methods that she used to gather those pictures, do you? 13:49:26 13:49:27 13:49:29

A. No. 13:49:33

Q. You agree, though, however, as reflected in paragraph 73 of your expert report -- in the second sentence, it says, "The specification of the '280 patent explains that 'the rate-limiting factor in the release of the drug is therefore controlled diffusion 13:50:07 13:50:08 13:50:12 13:50:18 13:50:23 13:50:26

of the drug from the matrix rather than erosion, dissolving or chemical decomposition of the matrix.'" 13:50:29 13:50:31 13:50:34

Correct? 13:50:38

A. Correct. 13:50:40

Q. And you also understand that in the term "diffusion" as construed in -- by the court, it permits some erosion, don't you? 13:50:40 13:50:43 13:50:50

A. I would admit to a very limited amount of erosion. 13:50:54 13:50:57

Q. And you admit that the court's construction, though, says that the rate-controlling release mechanism is primarily diffusion; correct? 13:51:03 13:51:04 13:51:06 13:51:08

A. Can you point me back to that phrase? 13:51:13 13:51:15

Q. Sure. 13:51:15

If you take a look at "Dissolution diffusion," page 8, Term No. 58 of the '280 patent. 13:51:16 13:51:20 13:51:26

(Witness peruses the exhibit.) 13:51:30

A. Sorry, where is it specifically? 13:51:49

Q. Page 8? 13:51:51

A. Page 8, yes. 13:51:52

Q. "Dissolution diffusion" under 13:51:52

Term No. 58 in the agreed construction. 13:51:58

A. Oh, yes. 13:52:02

(Witness peruses the exhibit.) 13:52:03

A. The question was again, please? 13:52:05

Q. You agree that the court's construction requires that the rate of release is at a rate "primarily controlled by the rate of diffusion"; correct? 13:52:07 13:52:10 13:52:12 13:52:18

A. Correct. 13:52:19

Q. Doesn't mean there can't be other factors in effect; correct? 13:52:20 13:52:22

MR. LANDMON: Objection. 13:52:28

I think it misconstrues the construction, and that question's vague and ambiguous. 13:52:31 13:52:34 13:52:36

THE WITNESS: Can you ask me -- 13:52:41

BY MR. GAEDE: 13:52:43

Q. Sure. 13:52:43

A. -- the question again. 13:52:44

Q. The rate of release doesn't have to be absolutely controlled by the rate of diffusion, it has to be primarily controlled by the rate of diffusion; correct? 13:52:45 13:52:47 13:52:50 13:52:52

A. In reading these words, yes. 13:52:58

Q. And you would agree that some 13:53:03

erosion is contemplated in the patent, correct, during the release of the drug? 13:53:04 13:53:07

A. Very little. 13:53:23

Q. Did your counsel bring to your attention a claim construction order in the litigation involving Depomed and Lupin? 13:53:25 13:53:27 13:53:30

A. No. 13:53:34

Q. So you're not aware that the judge in that case said that some erosion is permitted? 13:53:35 13:53:36 13:53:39

A. I'm not aware of that. 13:53:41

Q. If some erosion were permitted, would that change your opinion? 13:53:44 13:53:50

A. Possibly. 13:53:51

Q. Okay. Let's take a look at oval, everyone's favorite topic. 13:54:10 13:54:16

Now, we can agree, sir, that -- would you turn your attention, please, to page 8 of your expert report where you have the construction set forth. 13:54:55 13:55:12 13:55:16 13:55:20

A. Yes. 13:55:27

Q. That's the definition in the construction of "oval" as set forth in the right-hand column that says, "Any curve that is closed and concave towards the center where 13:55:28 13:55:30 13:55:34 13:55:36

the geometric form bounded by the closed curve has a first or second orthogonal axes of unequal length"? 13:55:42 13:55:44 13:55:48

A. Yes. 13:55:49

The question was, though? 13:55:49

Q. That's the construction of "oval"? 13:55:51 13:55:51

A. Yes. 13:55:52

Q. Now, in your section, though, on the '962 patent, you don't apply that construction. 13:55:54 13:55:56 13:56:01

A. No. 13:56:04

Q. So you don't apply the court's construction of "oval" in the '962 to the Actavis dosage forms, do you? 13:56:11 13:56:13 13:56:18

A. No. I honestly had a difficulty understanding the construed claim language. 13:56:21 13:56:24

Q. Did you ask your counsel for clarification? It's one they stipulated to. 13:56:30 13:56:32

A. I did. 13:56:36

Q. And did they explain it to you? 13:56:36

A. I was not given a clear definition, no. 13:56:42 13:56:44

Q. So as you look at the two pictures -- you have two pictures of the 13:56:46 13:56:48

Actavis dosage form on page 34 of your report? 13:56:49

A. Yes. 13:56:52

Q. On the left-hand side, the picture there, isn't that a curve that is closed and concave towards the center, where the geometric form bounded by the closed curve has a first and second orthogonal axes of unequal length? 13:56:54 13:56:58 13:57:01 13:57:04 13:57:07 13:57:11

A. It's -- as I stated previously, it's difficult for me to understand that claim language. 13:57:14 13:57:16 13:57:18

Q. Okay. So you didn't put that difficulty in your expert report and bring that to the court's attention, did you? 13:57:18 13:57:22 13:57:24

A. (Shakes head in the negative.) 13:57:27

Q. And you did not apply the court's construction, did you? 13:57:28 13:57:30

A. No. 13:57:32

Q. What you relied upon for "oval" is a specific tableting specification manual; correct? 13:57:42 13:57:45 13:57:50

A. Correct. 13:57:53

Q. And that's all that you relied upon in rendering your opinion set forth on the '962 patent as to whether the Actavis 13:58:02 13:58:04 13:58:07

dosage forms constitute an oval or not; correct? 13:58:11 13:58:13

A. That's the only exhibit, yes. 13:58:15

MR. GAEDE: Why don't we take a short break. He needs to change the tape. 13:58:23 13:58:24 13:58:25

THE VIDEOGRAPHER: The time on the video monitor is 1:58 p.m. We're off the record. This ends Media 3. 13:58:27 13:58:27 13:58:32

(Recess from the record.) 14:14:15

THE VIDEOGRAPHER: We are back on the record. The time on the video monitor is 2:14 p.m. This starts Media 4. 14:14:16 14:14:16 14:14:18 14:14:44

BY MR. GAEDE: 14:14:45

Q. Sir, I'd like to turn your attention to your opinions on the '927 patent that begin at page 36, 37, 38 of your expert report. 14:14:46 14:14:47 14:14:50 14:14:54

A. Okay. 14:14:54

Q. First of all, in Subsection A of the report at page 37, with respect to the 37 -- with respect to the '927 patent, your opinions are the same as in connection with the '280 patent for the issue of retention in 14:14:56 14:14:59 14:15:04 14:15:08 14:15:11

the stomach during the fed mode; correct? 14:15:16

A. Correct. 14:15:20

Q. Except that here we -- you and I can both agree there's no express pyloric diameter requirement as you say is present in the '280 patent; correct? 14:15:21 14:15:23 14:15:28 14:15:30

A. Not of pyloric -- no reference to the pylorus. 14:15:34 14:15:37

Q. Is it fair to say that other than your measurements specifically tied to the 12.8 millimeters, the statements and opinions you render with respect to the '280, other ones, that applies here to the '927; correct? 14:15:48 14:15:48 14:15:53 14:15:56 14:15:59

A. Yes. Generally, yes. 14:16:03

Q. And as you note, the court's construction is the same? 14:16:12 14:16:14

A. Yes. 14:16:21

Q. Let's turn to -- so your opinions don't in any way differ with respect to the '280; correct? 14:16:21 14:16:23 14:16:25

A. Correct. 14:16:27

Q. With respect to Subsection B of your opinion on the '927 patent, "By diffusion for at least five hours"? 14:16:31 14:16:33 14:16:37

A. Yes. 14:16:41

skill in the art would understand that dosage forms that the patentee had given up dosage forms that release drug primarily by a nondiffusional mechanism." 14:22:45 14:22:47 14:22:50 14:22:52

Do you see that? 14:22:56

A. Excuse me. I didn't -- I was at the beginning of 97 -- 14:22:57 14:22:58

Q. Sorry. Go ahead and read it. That's fine. Go ahead and read the paragraph if you need to and then we'll ask the question. 14:23:00 14:23:01 14:23:03 14:23:04

(Witness peruses the exhibit.) 14:23:05

A. Okay. 14:23:21

Q. At the end there, you write, "For these reasons, one of ordinary skill in the art would understand that dosage forms that the patentee had given up dosage forms that release drug primarily by a nondiffusional mechanism." 14:23:23 14:23:25 14:23:27 14:23:31 14:23:35 14:23:38

Correct? 14:23:38

A. Correct. 14:23:41

Q. And by a non -- "primarily by a nondiffusional mechanism," that's referring to -- in your opinion, to the possibility of erosion becoming the primary mechanism of 14:23:45 14:23:49 14:23:51 14:23:54

release; correct? 14:23:58

A. Possibly, yes. 14:23:59

Q. For this highly soluble drug? 14:24:02

A. Yes. 14:24:04

Q. But it's correct that you 14:24:10

understand the claim requirement by diffusion 14:24:11

over at least five hours, that it be primarily 14:24:14

by diffusion over at least five hours; 14:24:16

correct? 14:24:18

(Witness peruses the exhibit.) 14:24:25

A. Yes. 14:24:32

Q. We've talked about Subsection C 14:24:35

on Claim 26. That's the 85 percent. 14:24:38

Moving along -- oh, let's go to 14:24:44

your opinion on Claim 10, 1 and 10 of the 14:24:52

'989. 14:24:56

A. It's number 11; is that right? 14:25:05

Q. I'm sorry, 11, yes. 14:25:07

A. That's okay. 14:25:09

Q. My Roman numerals are starting to 14:25:09

blur in the afternoon. 14:25:13

Starting at paragraph 102. 14:25:14

A. Okay. 14:25:16

Q. Here you have Claim 1 of the 14:25:16

'989? 14:25:17

THE VIDEOGRAPHER: The time on the video monitor is 2:50 p.m. We're off the record. This ends our deposition. 14:50:10 14:50:11 14:50:14 14:50:16

(TIME NOTED: 2:50 P.M.)

STATE OF NEW YORK)
ss:
COUNTY OF WESTCHESTER)

I, DAVID R. FRIEND, the witness herein, having read the foregoing testimony of the pages of this deposition, do hereby certify it to be a true and correct transcript, subject to the correction, if any, shown on the attached page.

_____
DAVID R. FRIEND

Subscribed and sworn before me
this _____ day of_____, 2014.

_____

STATE OF NEW YORK)
ss:
COUNTY OF NEW YORK)

I, Eileen Mulvenna, Notary Public within and for the State of New York, do hereby certify:

That I reported the proceedings in the within entitled matter, and that the within transcript is a true record of said proceedings.

I further certify that I am not related to any of the parties to the action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 29th day of March, 2014.

_____

Eileen Mulvenna, CSR/RMR